*THIS OPINION WAS NOT WRITTEN FOR PUBLICATION*

93-2008

This opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

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Paper No. 14

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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*Ex parte* LOWELL SAFERSTEIN
and STEPHEN J. WOLF

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Appeal No. 93-2008
Application 07/528,002[1]

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ON BRIEF

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Before RONALD H. SMITH, WINTERS, and WILLIAM F. SMITH, *Administrative Patent Judges*.

WINTERS, *Administrative Patent Judge*.

DECISION ON APPEAL

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[1] Application for patent filed May 23, 1990.

This appeal was taken from the examiner's decision refusing to allow claims 1 through 17, which are all of the claims in the application.

Claim 1 is representative:

1. An anhydrous hemostatic paste composition comprising a hemostatic effective amount of thrombin substantially uniformly dispersed in a polyethylene glycol base.

The references relied on by the examiner are:

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|---|---|---|
| Altshuler | 4,363,319 | Dec. 14, 1982 |
| Lill et al. (Lill) | 4,496,653 | Jan. 29, 1985 |
| Cioca | 4,515,637 | May 7, 1985 |
| Silbering et al. (Silbering) | 4,696,812 | Sep. 29, 1987 |
| Saferstein et al. (Saferstein) | 4,752,466 | June 21, 1988 |

Rotoli et al. (Rotoli), "Optimizing and Stabilizing Thrombin Activity", Chemical Abstracts, 107:35563r, 1986.

Remington's Pharmaceutical Sciences (Remington's reference), Publisher: Mack Publishing Co., pp. 1251-1252 and 1535 (1975).

The issues presented for review are: (1) whether the examiner correctly rejected claims 1 through 17 under 35 USC 103 as unpatentable over the combined disclosures of Altshuler, Silbering, Cioca and Saferstein; and (2) whether the examiner correctly rejected claim 1 under 35 USC 103 as unpatentable over Lill, Altshuler, Silbering, or Rotoli.

## OPINION

Our deliberations in this matter have included evaluation and review of the following materials: (1) the instant specification and all of the claims on appeal; (2) appellants' brief before the Board; (3) the examiner's answer; and (4) the prior art references cited and relied on by the examiner.

Having carefully considered those materials, we agree with appellants that the subject matter sought to be patented in claims 1 through 17 would not have been obvious at the time the invention was made to a person having ordinary skill in the art based on teachings found in the cited references. Accordingly, for the reasons discussed infra, we reverse the examiner's §103 rejections. We enter a new ground of rejection under the provisions of 37 CFR 1.196(b).

## THE EXAMINER'S REJECTIONS

Initially, we invite attention to the examiner's citation of the Remington's reference in section (8) of the answer entitled "new prior art". According to the examiner, that reference is cited "to show a well known fact in the art", although "[n]o new prior art has been applied in this examiner's answer". Again,

see the answer, page 3, section (8). Be that as it may, the examiner discusses the Remington's reference in setting forth grounds of rejection in the answer, section (9). See particularly pages 4 and 5 of the examiner's answer. In section (12) of the answer, the examiner states that

> In view of the added discussion of the Remington's reference cited in rebuttal of appellants' arguments, appellant is [sic, appellants are] given a period of TWO MONTHS from the mailing date of this examiner's answer within which to file a reply to any new issues raised in this answer.

This state of affairs is most confusing. Regardless of the statement that "[n]o new prior art has been applied in this examiner's answer", we find that the examiner does, in fact, apply the Remington's Pharmaceutical Sciences reference in section (9) of the answer entitled "Grounds of Rejection". This is so, even though the examiner does not positively include the reference in the statement of either rejection under 35 USC 103.

As stated in *In re Hoch*, 428 F.2d 1341 n.3, 166 USPQ 406 n.3 (CCPA 1970),

> Where a reference is relied on to support a rejection, whether or not in a "minor capacity", there would appear to be no excuse for not positively including the reference in the statement of rejection.

On these facts, we admonish the examiner "for not positively including the reference in the statement of rejection". Where,

as here, the examiner cites the Remington's reference in the answer, labels that reference "new prior art", and discusses that reference in setting forth each ground of rejection, we find that the Remington's reference should have been positively included in the statement of each §103 rejection. By omitting that reference from the statement of each rejection and by suggesting that the reference is cited merely "in rebuttal of appellants' arguments", the examiner commits procedural error and contributes to a substantial amount of confusion in the administrative record.

In any event, in our deliberations, we have considered the Remington's Pharmaceutical Sciences reference in its entirety. Taking into account the full import of that reference, we find that the examiner failed to establish a *prima facie* case of obviousness in setting forth either of the §103 rejections before us.

Appellants' contribution relates to a "hemostatically effective, convenient, and storage stable form of thrombin ideally suited for surgical use". See the instant specification, page 2. As reflected in representative claim 1, appellants' claimed composition is neither a dry powder nor an aqueous saline solution but rather "an anhydrous hemostatic paste". Specifically, claim 1 calls for

> An anhydrous hemostatic paste composition comprising a hemostatic effective amount of thrombin substantially uniformly dispersed in a polyethylene glycol base.

In setting forth each §103 rejection before us, the examiner recognizes that the physical form of the claimed composition differs from the closest prior art compositions. According to the examiner, however, the anhydrous paste composition recited in appellants' claims "would have merely been a matter of design choice" or "would have been an obvious matter of choice of form for delivery of a thrombin composition". See the examiner's answer, page 6. In this manner, the examiner dismisses the very essence of appellants' contribution, namely, the physical form of the claimed composition, as a mere "matter of choice" or "matter of design choice" without an adequate factual foundation in the record. As stated in *In re Warner*, 379 F.2d 1011, 154 USPQ 173 (CCPA 1967), the legal conclusion of obviousness must be supported by facts. Where the legal conclusion is not supported by facts it cannot stand. On the particular facts of this case, we believe that the examiner relies on an impermissible degree of hindsight in concluding that the subject matter sought to be patented would have been obvious. Based on the evidence cited by the examiner, including the Remington's Pharmaceutical Sciences reference, we conclude that the claimed subject matter would have been unobvious. We do so notwithstanding the simplicity of

appellants' invention viewed from hindsight, for simplicity and hindsight are improper criteria for resolving the issue of obviousness. *In re Horn*, 203 USPQ 969 (CCPA 1979). The examiner's §103 rejections are reversed.

NEW GROUND OF REJECTION

Under the provisions of 37 CFR 1.196(b), we enter the following new ground of rejection.

Claims 1 through 6 and 13 through 17 are rejected under 35 USC 103 as unpatentable over the combined disclosures of Japanese Kokai 132,842,[2] Silbering and the Remington's Pharmaceutical Sciences reference.

Japanese Kokai 132,842 discloses the combination of a hemostatic effective amount of thrombin and a suitable ointment base wherein the components are "kneaded to homogeneity and uniformity". The Japanese Kokai reference further discloses that "[a]s the blend ratio of thrombin, about 100-10,000 units per 1 g

[2] In the information disclosure statement filed January 2, 1991, appellants cite Japanese Kokai 132,842/1988 and supply an "excerpt translation" of that reference. In entering this new ground of rejection, we rely on the "excerpt translation".

of ointment are desirable" and names glycerine and glycols, *inter alia*, as suitable ointment bases.

Silbering discloses that "[g]lycerol [glycerine] and other polyols, such as polyalkylene glycols and preferably polyethylene glycols, are typical ingredients in many commercial thrombin-based products" [emphasis added]. See Silbering, column 2,lines 44 through 47. Silbering further discloses that thrombin and its preparations are useful during surgical procedures to control bleeding, and that thrombin and its preparations may be applied in combination with a fibrous gauze material. The Remington's Pharmaceutical Sciences reference discloses that polyethylene glycols, having substantially the same molecular weight or molecular weight range recited in appellants' claims, are useful pharmaceutical ointments.

We are persuaded that a person having ordinary skill in the art, armed with the disclosures of Silbering and the Remington's Pharmaceutical Sciences reference, would have found it obvious to select a suitable polyethylene glycol for use as the ointment base in the invention disclosed by Japanese Kokai 132,842. In this manner, a person having ordinary skill in the art would have arrived at appellants' anhydrous "paste" composition with a reasonable expectation that the "paste" will successfully reduce

bleeding at the hemorrhaging cite of a mammal. On the strength of these references, we hold that the subject matter sought to be patented in claims 1 through 6 and 13 through 17 would have been *prima facie* obvious.

On return of this application to the examining group, we suggest to both appellants and the examiner that (1) the complete English translation of Japanese Kokai 132,842/1988 be placed of record, and (2) further evaluation of the Japanese Kokai reference and discussion of same be based on the complete English translation.

We note appellants' statement in the specification that

> In accordance with purposes of the invention, as embodied and fully described herein, the invention comprises a freeze-dried hemostatic paste composition comprising a hemostatic effective amount of thrombin in a polyethylene glycol base [emphasis added].

See the instant specification, page 2, lines 23 through 27. Further in this regard, note the statement on page 8 of the specification that

> The thrombin is an aqueous solution as it is admixed with the polyethylene glycol and must be freeze-dried to provide a smooth non-gritty paste. Mixing of powdered thrombin with polyethylene glycol will give a lumpy paste as will mixing an aqueous solution of thrombin with polyethylene glycol and air drying [emphasis added].

Nevertheless, Example 5 in the specification mixes powdered thrombin with polyethylene glycol and does not freeze-dry. On return of this application to the examining group, we suggest that the examiner require appellants to explain or clarify this apparent internal inconsistency in the specification.

The examiner's decision is reversed.

Any request for reconsideration or modification of this decision by the Board of Patent Appeals and Interferences based upon the same record must be filed within one month from the date of the decision (37 CFR 1.197). Should appellants elect to have further prosecution before the examiner in response to the new rejection under 37 CFR 1.196(b) by way of amendment or showing of facts, or both, not previously of record, a shortened statutory period for making such response is hereby set to expire two months from the date of this decision.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR 1.136(a).

*REVERSED; 37 CFR 1.196(b)*

RONALD H. SMITH
Administrative Patent Judge

SHERMAN D. WINTERS
Administrative Patent Judge

WILLIAM F. SMITH
Administrative Patent Judge

BOARD OF PATENT APPEALS AND INTERFERENCES

Appeal No. 93-2008
Application 07/528,002

Robert L. Minier
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003